

DATE OUT: 02/SEP/2008

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FEE; SUBJECT: **PRODUCT CHEMISTRY REVIEW OF: AN End-Use Product [X]**
DP BARCODE#: D355724 EPA RECEIVED DATE: 25/AUG/2008 REG NO.: 5905-LTO
PRODUCT: HM-0429 MRIDs: 474944-01 & 475097-01 **FOOD & NON-FOOD USE [X]**
COMPANY NAME : Helena Chemical Company ACTION CODE: R300
PPC NUMBER OF THE TGAI IN THE PRODUCT 107201 DECISION NO.: 398243

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505P)

TO: 23 Joanne Miller/Tracy White
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8/26/08 1031/08

INTRODUCTION:

In a letter dated 14/JUL/2008, the applicant requested a "me-too" registration of subject product claiming its similarity to Velpar L, Reg. No. 352-392. In support of the application, the applicant included product chemistry data, a proposed basic CSF dated 19/MAY/2008, a proposed label EPA received on 31/JUL/2008, Formulator's Exemption Statement, Certificate With respect to Citation of Data, and Data Matrix

FINDINGS:

1. The subject product was produced by a non-integrated formulation system, meaning that the active ingredient in the product is registered. The product contains 25% hexazinone [REDACTED]. The product was formulated in the US.
2. The subject product, a herbicide, is intended for weed control in crops and non-crop areas.
3. The subject product is substantially similar in composition to Velpar L, Reg. No. 352-392. Both products contain the same active ingredient at the same nominal concentration, upper/lower certified limits and approximately, the same physical/chemical properties. Exceptions: [REDACTED]
- 4a. The applicant should be advised to submit the results of product's storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320) identified as data gaps.
- 4b. Except for the data gaps in Finding 4(a) above, the submitted product chemistry data is adequate and support "me-too" registration of subject product.
5. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

source, hexazinone, Reg. No. 352-392. An analytical method was included with this submission, MRID #474944-01, entitled: "CIPAC Method 1999, Hexazinone 374." The method is reviewed in this memorandum.

6. The label claim nominal concentrations of 25% hexazinone is consistent with that in the basic CSF dated 19/MAY/2008. Both are in compliance with the regulations of PR Notice 91-2. Further, the label storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.
7. The proposed basic CSF dated 19/MAY/2008, was filled out correctly and completely and agree with the label claim nominal concentration. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed in the CSF have been approved for use in pesticide formulations intended for food and non-food uses.

CONCLUSIONS:

1. From the product chemistry view point, the subject product is substantially similar in composition to Velpar L, Reg. No. 352-392 (Finding 3 above).
2. After resolving Findings 4(a) above, the TRB will have no objections for a "me-too" registration of subject product. The proposed basic CSF dated 15/MAY/2008 and label EPA received on 31/JUL/2008 are acceptable as per findings 6 & 7 above.

REVIEW OF PRODUCT CHEMISTRY DATA (MRID #471842-01 & -02

1. A statement of data confidentiality dated 19/JUL/2008 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data has been removed to Confidential Appendix A.
2. A GLP statement dated 11/AUG/2008 was included with this submission to the effect that some of the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical source, hexazinone, Reg. No. 352-392.

An analytical method was included with this submission, MRID #474944-01, entitled: "CIPAC Method 1999, Hexazinone 374." The method, a high performance liquid chromatography (HPLC), is equipped with a UV detector using benzanilide as an internal standard. In this method equal amounts of the test substance and the internal

standard are dissolved in acetonitrile and 5 µl aliquots of the solution are injected into the HPLC. Detections was accomplished at 254 nm. The retention time for hexazinone 2.8 minutes and that of benzanilide at 4.4 minutes.

Method validation data regarding recovery, accuracy, precision, and linearity are adequate. Sample calculation was included with this submission.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

This product contains one registered technical source, plus [REDACTED]
[REDACTED] approved for use in pesticide formulations intended for food and non-food uses (refer to product's basic CSF dated 19/MAY/2008).

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential Appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential appendix A.

830-1750 Certified Limits:
Refer to Confidential appendix A.

Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800 (40 CFR 158.155 to 158.180)

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	474944-01
.1600 Description of materials used to produce the product	Y	474944-01
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	474944-01
.1670 Discussion of formation of impurities	Y	474944-01
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	474944-01
.1800 Enforcement analytical method	Y	474944-01
Explanations: Y =The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.		

Physical and Chemical Properties of Subject Product, 40CFR158.190

Except for product's storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320), the remaining physical/chemical properties included with this submission, MRID #475097-01 are acceptable.

Confidential Appendix A**830-1600 Description of Materials Used to Produce the Product:**

One registered technical grade of an active ingredient plus [REDACTED]
[REDACTED] approved for use in pesticide formulations intended for food and non-food uses
(refer to the proposed basic CSF dated 19/MAY/2008).

830-1650 Description of Formulation Process:**830-1670 Discussion of Formation of Impurities:**

The applicant reported no impurities $\geq 0.1\%$ by weight were known to be formed during formulation and storage of the product. There was no chemical reaction in the process.

830-1700 Preliminary Analysis:

Not required for this non-integrated product.

830-1750 Certified Limits:

The applicant reported the same certified limits as those in product's basic CSF dated 19/MAY/2008.